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Value of standard radiographs, computed tomography, and magnetic resonance imaging of the lumbar spine in detection of intraoperatively confirmed pedicle screw loosening-a prospective clinical trial

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Abstract: BACKGROUND CONTEXT Pedicle screw loosening is common after spinal fusion and can be associated with pseudoarthrosis and pain. With suspicion of screw loosening on standard radiographs, CT is currently considered the advanced imaging modality of choice. MRI with new metal artifact reduction techniques holds potential to be sensitive in detection of screw loosening. The sensitivity and specificity of either of the imaging modalities are yet clear. PURPOSE To evaluate the sensitivity and specificity of three different image modalities (standard radiographs, CT, and MRI) for detection of pedicle screw loosening. STUDY DESIGN/SETTING Cross-sectional diagnostic study. PATIENT SAMPLE Forty-one patients (159 pedicle screws) undergoing revision surgeries after lumbar spinal fusion between August 2014 and April 2017 with preoperative radiographs, CT, and MRI with spinal metal artifact reduction (STIR WARP and TSE high bandwidth sequences). OUTCOME MEASURES Sensitivity and specificity in detection of screw loosening for each imaging modality. METHODS Screw torque force was measured intraoperatively and compared with preoperative screw loosening signs such as peri-screw edema in MRI and peri-screw osteolysis in CT and radiographs. A torque force of less than 60 Ncm was used to define a screw as loosened. RESULTS Sensitivity and specificity in detection of screw loosening was 43.9% and 92.1% for MRI, 64.8% and 96.7% for CT, and 54.2% and 83.5% for standard radiographs, respectively. CONCLUSIONS Despite improvement of MRI with metal artifact reduction MRI technique, CT remains the modality of choice. Even so, CT fails to detect all loosened pedicle screws.

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Value of standard radiographs, CT and MRI of the lumbar spine in detection of intraoperatively confirmed pedicle screw loosening – a prospective clinical trial

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Abstract

Background Context

Pedicle screw loosening is common after spinal fusion and can be associated with pseudoarthrosis and pain. With suspicion of screw loosening on standard radiographs, CT is currently considered the advanced imaging modality of choice. MRI with new metal artifact reduction techniques holds potential to be sensitive in detection of screw loosening. The sensitivity and specificity of either of the imaging modalities are yet clear.

Purpose

To evaluate the sensitivity and specificity of three different image modalities (standard radiographs, CT and MRI) for detection of pedicle screw loosening.

Study Design/Setting

Cross-sectional diagnostic study

Patient Sample

Forty-one patients (159 pedicle screws) undergoing revision surgeries after lumbar spinal fusion between August 2014 and April 2017 with preoperative radiographs, CT and MRI with spinal metal artifact reduction (STIR WARP and TSE high bandwidth sequences).

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Outcome Measures

Sensitivity and specificity in detection of screw loosening for each imaging modality.

Methods

Screw torque force was measured intraoperatively and compared with preoperative screw loosening signs such as peri-screw edema in MRI and peri-screw osteolysis in CT and radiographs. A torque force of less than 60Ncm was used to define a screw as loosened.

Results

Sensitivity and specificity in detection of screw loosening was 43.9% and 92.1% for MRI, 64.8% and 96.7% for CT, and 54.2% and 83.5% for standard radiographs, respectively.

Conclusions

Despite improvement of MRI with metal artifact reduction MRI technique, CT remains the modality of choice. Even so, CT fails to detect all loosened pedicle screws.

INTRODUCTION

Pedicle screw fixation has become one of the standard methods of instrumentation for spinal fusion. The purpose of pedicle screw fixation is to increase the stability of the segments in order to increase the chance of bony fusion. One common complication is loosening of pedicle screws at the bone interface which, in the presence of pseudarthrosis, often result in revision surgery.

The frequency of screw loosening varies widely throughout the literature. Rates from 1% to 40% are reported [1–4] depending on age, bone quality and number of fused levels [5]. However, in most reports, the judgement of screw fixation is based on plain radiograph assessment [6–11]. A radiolucent zone surrounding a pedicle screw can be a sign of screw loosening, but a loose screw is not always surrounded by a radiolucent zone [7]. Also, more than 50% of radiolucent zones can disappear within 2 years if detected within 6 months after operation [11]. However, radiolucent zones persisting for 2 years or longer after surgery are highly associated with pseudarthrosis [11].

CT, particularly thin-section helical CT [12], is currently considered the diagnostic imaging modality of choice for detection of screw loosening and, potentially, pseudarthrosis, though screw loosening does not always imply pseudarthrosis. Recent studies have investigated the role of SPECT/CT in detecting spinal

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implant loosening with better accuracy though practicality and radiation exposure is a concern [13,14]. MRI, with the advantage of avoiding ionizing radiation and better soft tissue visualization [15], is increasingly used in assessment of a patient with spinal disorders. However, concomitant magnetic-susceptibility artifacts seen with metallic implants can hinder images [16,17]. Recent MRI advances and use of non-ferromagnetic titanium implants has improved spinal images with hardware in place [18–21]. In turn, newer MRIs may prove a valuable option in detecting screw loosening.

Recent reports have shown promise using MRI and metal artifact reduction sequences of detection of implant loosening in the knee and hip [22–24]. Studies focusing on pedicle screw loosening are lacking. The aim of this study was to assess the sensitivity and specificity of the most commonly used imaged modalities (standard radiographs, CT, and MRI) in detection of pedicle screws loosening following an attempted posterior lumbar fusion.

MATERIAL AND METHODS

Ethical approval from the local ethics committee was obtained, and the study was registered at the Swiss National Clinical Trials Portal (registration number: SNCTP000000314).

Study population

Forty-one patients (22 females, 19 males, mean age 67.3±10.9 years [range: 27-89]) were enrolled between August 2014 and April 2017 at a single institution with planned revision surgery for painful pseudoarthrosis, adjacent segment disease or proximal junction kyphosis. Further inclusion criteria were informed consent, age older than 18, and titanium instrumentation. The time interval between index surgery and revision surgery was 3.05±3.12 years (range: 0.06-13.50).

In total, 159 screws were examined with MRI, CT, and standard radiographs prior to intraoperatively quantifying each screw hold with a torque-measuring device. The time interval between the date of MRI, CT and radiographs and date of revision surgery was 36±40.7 days (range: 1-157 days), 48.7±58.78 days (range: 1-304 days) and 29.2±39.42 (range: 0-188) respectively.

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MRI, CT and radiographic protocol

All MRI scans were performed at the University Hospital Balgrist on a 1.5-T scanner (Magnetom Avanto, Siemens Healthcare, Erlangen, Germany). The software used was Syngo MR VD13, Siemens Healthcare. The following imaging sequences of lumbar MRI were employed: coronal short tau inversion recovery (STIR) WARP, transverse T2w turbo spin-echo (TSE) high bandwidth, sagittal T2w TSE high bandwidth, sagittal T1w TSE high bandwidth. WARP is defined as high receiver bandwidth of 610 – 620 Hz/px and view-angle tilting (VAT) 100 %, and the STIR WARP sequence includes an optimized inversion pulse that adapted to the high receiver bandwidth [25].

All CT scans were performed on a 64-MDCT scanner (Brilliance, Philips Healthcare) using standard "bone" protocol (120 KV; 250 mAs with intensity modulation; 1 s rotation time; slice collimation, 64 x 0.625 mm). Image reconstruction produced images with a slice thickness of 2 mm at a 1 mm increment. Automatic rigid image registration was performed using the SYNGO multimodality software (Siemens Healthcare, Germany).

Conventional lateral and anteroposterior (AP) radiographs were taken at least 6 months before revision surgery.

Image analyses

All images were assessed separately by two well experienced musculoskeletal radiologists (Reader 1: R.S. senior consultant and Reader 2: N.F. consultant). Analyses of all image sets were performed by commercial Picture Archiving and Communication System (PACS) viewer Merlin 5.2. (Phoenix-PACS, Freiburg, Germany).

The readers independently evaluated MRI, CT, and radiographs without knowledge of the intraoperative findings.

MRI

Investigated signs of screw loosening in MRI were: presence of peri-screw edema (Reader 1 and 2) and size of peri-screw edema (Reader 2). Maximal width of each sign was recorded irrespective of the length. (Fig. 1)

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CT and radiographs

Maximum size of peri-screw osteolysis if present, also known as radiolucent zones, was recorded irrespective of the length of the lucency and slice of occurrence in CT. The influence of these signs on screw torque was analyzed separately. (Fig. 2)

Surgical protocol

All patients underwent revision surgery during which all pedicle screws hold was quantified. After exposing the implants, rods were removed separately, and screw heads were freed from soft tissue. A torque meter (Model TT03, Mark-10 Corporation, New York, USA) with an appropriate screwdriver (Fig. 3) was inserted and the maximum torque was measured while unscrewing the screw. Screws were then replaced, and the subsequent surgery was performed as usual and independent of the study.

Statistical analysis

All values are given as the mean ± 1 SD. Interrater reliability was assessed using two-way random effects single measures intra-class correlation (ICC (2,1)) for interval-scaled values and Cohens Kappa for nominal variables. Associations between interval-scaled radiographic predictor variables with screw loosening were investigated using separate ordinary least squares linear regressions including a constant of peri-screw osteolysis and size of edema on natural log-transformed torque values. A p-value <0.05 was considered statistically significant. All statistical analyses were performed with SPSS software (version 24.0; SPSS Inc., Chicago, IL, USA).

RESULTS

Intraoperative Measures

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The overall screw torque force was 144.5±131.7 Ncm (range: 0-500 Ncm). Screw loosening was defined as a screw torque <60 Ncm since the distribution of screw torques seems to contain two overlapping normal distributions, one for loosened screws (Mean: 13.4±17.3 Ncm) and one for firm screws (161.9±85.9 Ncm) with an intersection point at 60 Ncm (Fig. 4). Fifty-five loosened screws (<60 Ncm) and 104 firm screws (>60 Ncm) were identified.

Analysis of peri-screw osteolysis in radiographs

Linear regression analysis of the radiographic score on ln-transformed (natural logarithm) torque values revealed a significant ($p < 0.001$) negative association of peri-screw osteolysis with torque (Fig. 5) in the form: $\mathrm{Torque} = e^{5.015-0.574*\mathrm{RadScore}}$. R^2 was 0.166. This readout was only done by one reader (reader 1) since the role of radiographs in detecting screw loosening has already been previously examined [7].

Analysis of peri-screw osteolysis in CT

For both readers, linear regression analysis of the radiographic score on ln-transformed torque values revealed a significant ($p < 0.001$) negative association of peri-screw osteolysis with torque (Fig. 6) in the form: $\mathrm{torque} = e^{4.975-0.553*\mathrm{RadScore}}$ (Reader 1) and $\mathrm{torque} = e^{4.950-0.445*\mathrm{RadScore}}$ (Reader 2). R^2 was 0.229 and 0.240 respectively. Intra-class correlation analysis for detecting radiolucent zones in a CT yielded good agreement of ICC = 0.860 ($p < 0.001$) in a two-way random effects model on a single measures approach.

Analysis of peri-screw bone edema in MRI

For both readers, presence of bone edema was significantly associated with a lower mean unscrew torque force (Fig. 7). For reader 1 mean unscrew torque without presence of bone edema was 159.45±132.32 Ncm versus 69.81±110.49 Ncm with presence of bone edema ($p = 0.001$). Similar results were measured by reader 2: 177.45±132.34 Ncm versus 21.78±23.03 Ncm respectively ($p < 0.001$).

Cohen’s Kappa revealed, however, a poor agreement between the two raters concerning presence of edema around the screw ($k = 0.289$, $p < 0.001$). There was agreement for 180 screws and no agreement in 43 screws.

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Linear regression analysis of the radiographic score on ln-transformed torque values revealed a significant ($p < 0.001$) negative association of edema size with torque (Fig. 8) in the form: $\mathrm{Torque} = e^{5.144-0.126*\mathrm{RadScore}}$. R^2 was 0.062.

Sensitivity and Specificity of each radiological modality

Since there might be no sharp cutoff torque for a loose screw, we also analyzed 80 Ncm and 40 Ncm as a cutoff to test for hypothesis stability. However, this had little effect on sensitivity and specificity in any modality (Table 1).

With a cutoff torque at 60 Ncm, the highest sensitivity was achieved by peri-screw osteolysis in CT (52.4%-64.8%), followed by peri-screw osteolysis in radiographs (54.2%). Sensitivity of MRI (34.5%-43.9%) was inferior to both, CT and radiographs.

Both readers achieved an excellent specificity using the modality peri-screw osteolysis in CT (97.8%-100%), whereas radiographs and MRI achieved lower values (83.5% and 77.4%-92.1%). Overall, peri-screw osteolysis in CT achieved best values with however an unacceptable sensitivity but good specificity (64.8% and 96.7% respectively). (Table 1)

DISCUSSION

The aim of this study was to assess the sensitivity and specificity of the most commonly used imaged modalities (standard radiograph, CT, MRI) in detection of pedicle screws loosening within a prospective trial with intraoperative quantification of screw loosening. Our results confirm that peri-screw osteolysis in CT is still the best indicator for screw-loosening after spinal fusion. However, the maximum sensitivity and specificity was 64.8% and 96.7% for CT, 54.2% and 83.5% for radiographs and 43.9% and 92.1% for MRI respectively.

These results indicate, that none of the modalities are sufficiently sensitive in detecting screw loosening, though CT seems to have reasonable specificity of screw loosening. In other words, if the CT shows peri-screw osteolysis, the screw is most likely loose. Sanden et al. reported similar results with 64% sensitivity and

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100% specificity for radiographs using intraoperative screw torque measurement as the gold standard [7]. To the authors' knowledge, there are no prior studies comparing CT with intraoperative torque as a reference. However, CT has been reported to be more sensitive than radiographs for detecting screw loosening [26,27]. Disadvantages of CT are high radiation exposure and its reduced ability to define soft tissues pathologies such as nerve compression, infections, scar tissue, bone edema and intradural pathologies compared to MRI [28–31]. Therefore, MRI is often indispensable in the investigation of ongoing symptoms following spinal fusion.

To the best knowledge of the authors, this is the first study investigating the role of MRI in detection of screw loosening. Previous studies have shown that postoperative MRI's with metal artifact reduction techniques including high bandwidth optimization, view angle tilting (VAT), multispectral imaging techniques multiacquisition variable resonance image combination (MAVRIC) and slice-encoding for metal artifact correction (SEMAC) may significantly reduce metal-induced artifacts and reliably improve visibility of anatomical structures such as the dural sac, nerve roots and bone-implant interface [25,32]. These techniques require significantly longer acquisition times and may not be feasible on a routine basis [33]. Therefore, we investigated in this study TSE with high bandwidth optimization and STIR WARP sequences which are known to have reasonable acquisition times. However, it remains unknown if sensitivity and specificity of MRI for detecting screw loosening would be improved using sequences with more acquisition time such as SEMAC or MAVRIC [20,22,23,25,34].

The focus of the study question was specifically to define sensitivity and specificity of current imaging modalities such as MRI, CT, and radiographs in detecting screw loosening. Inclusion criteria were therefore not reduced to patients suspected of painful pseudoarthrosis but all kind of indications for revision surgery after spinal fusion. We do not claim to report differentiation of the proportions of patients suffering from isolated pseudoarthrosis versus so-called painful screw loosening. It is, however, evident from a prior study that screw loosening is strongly associated with pseudoarthrosis when still present two years after surgery and that signs of screw loosening are seen in 93.3% of pseudoarthrosis [11]. Other signs, such as absence of fusion mass or osteolysis and edema around the intervertebral cage, can suggest pseudoarthrosis. These were not analyzed in this study.

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Despite its role in the evaluation of postoperative lumbar fusion patients, MRI has had little role in detecting pseudoarthrosis [35,36]. CT has been reported to be the most accurate modality [15,37], though intraoperative detection of pseudoarthrosis remains the gold standard [38,39].

Several other limitations need consideration if interpreting the here presented results. As shown in our study there seems to be no sharp screw torque cut-off that defines a loose screw. We did find an exponential relationship between screw torque and several loosening signs. This contrasts with the study by Sanden et al. [7], which defined 40 Ncm as a cut-off since no extraction torques between 40 and 75 Ncm were found. We could not detect such a clear gap in our data. However, there seemed to be two normal distributions, one of loosened screws and one of clearly firm screws with an intersection point around 60 Ncm. We therefore set our cut-off torque at 60 Ncm and compared this with other cut-off torques at 80 Ncm and 40 Ncm. Little change in sensitivity and specificity of each image modality was observed with this variation. A further limitation of this study is that only titanium-based implants were included. Since metal artifacts are much more extensive with other materials such as cobalt-chromium or stainless-steel [18,40–42], our results may not applicable to these materials.

Finally, it could be questioned if measurement of unscrew torque is the right parameter to determine screw loosening and whether pullout strength might be more suitable to define screw loosening. Several studies have shown that insertional torque does not necessarily correlate with axial pullout force and both parameters might be influenced by different factors [43–45]. Neither axial pullout force nor unscrew torque seems to adequately mimic physiological loading [44,46–49]. However, in vivo experiments allow only for unscrew torque measurements since both toggling and pullout experiments have a destructive nature that are not ideal for patients. There seems to be, nonetheless, some correlation between screw torque and the number of toggling cycles until failure occurs [44]. As far as the authors are aware, screw torque is the only intraoperative measurable parameter to quantify the screw-bone interface hold for in vivo human studies.

CONCLUSIONS

Standard radiographs, CT, or MRI are highly sensitive in detection of pedicle screw loosening. CT remains the most specific image modality for screw loosening.

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Figures

Figure 1:

MRI (Coronal short tau inversion recovery (STIR) WARP) showing the pedicle screw (arrow) and peri-screw edema (arrowheads) as a screw loosening sign.

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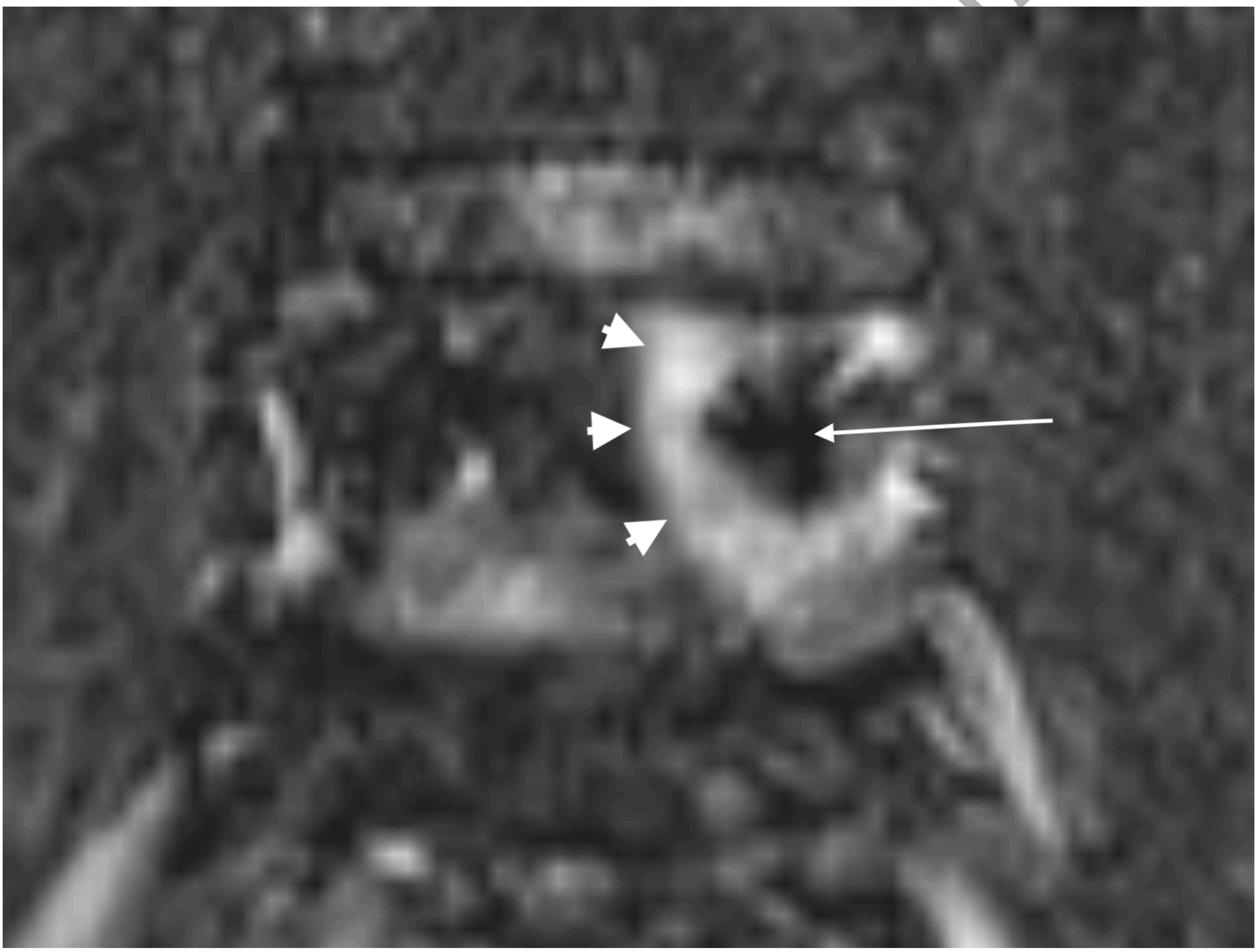

Figure 2:

Transverse CT showing two pedicle screws (arrow) with peri-screw osteolysis (arrowheads) as a screw loosening sign.

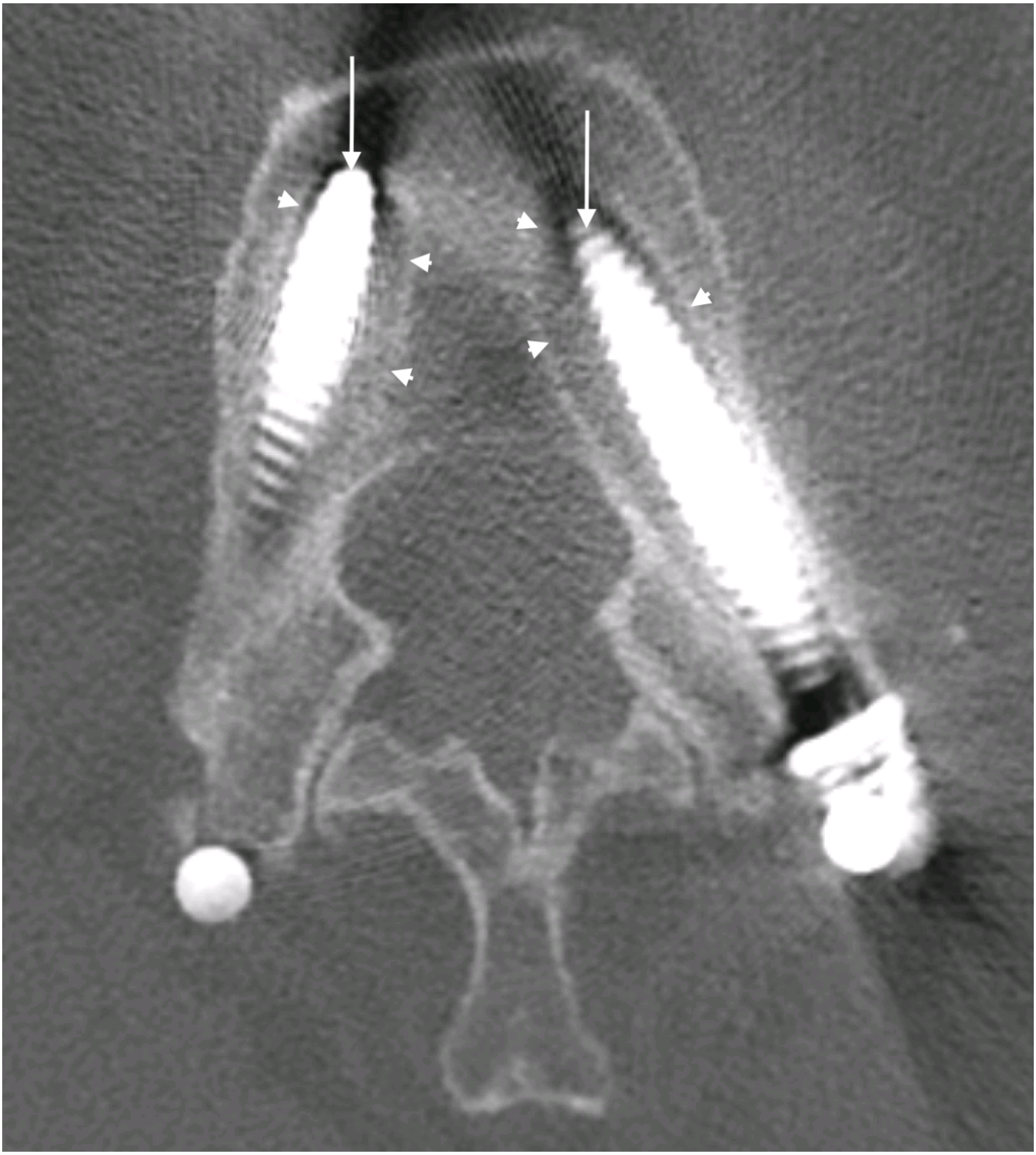

Figure 3:

Torque meter with exchangeable screwdriver for intraoperative screw torque measurement.

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Figure 4:

Distribution of screw torques shows an intersection point of two overlapping normal distributions at 60 Ncm. Screw loosening was therefore defined as a screw torque <60 Ncm. However, there might be a transition zone between loosened screw and firm screw shown (grey zone: 60 Ncm±20 Ncm).

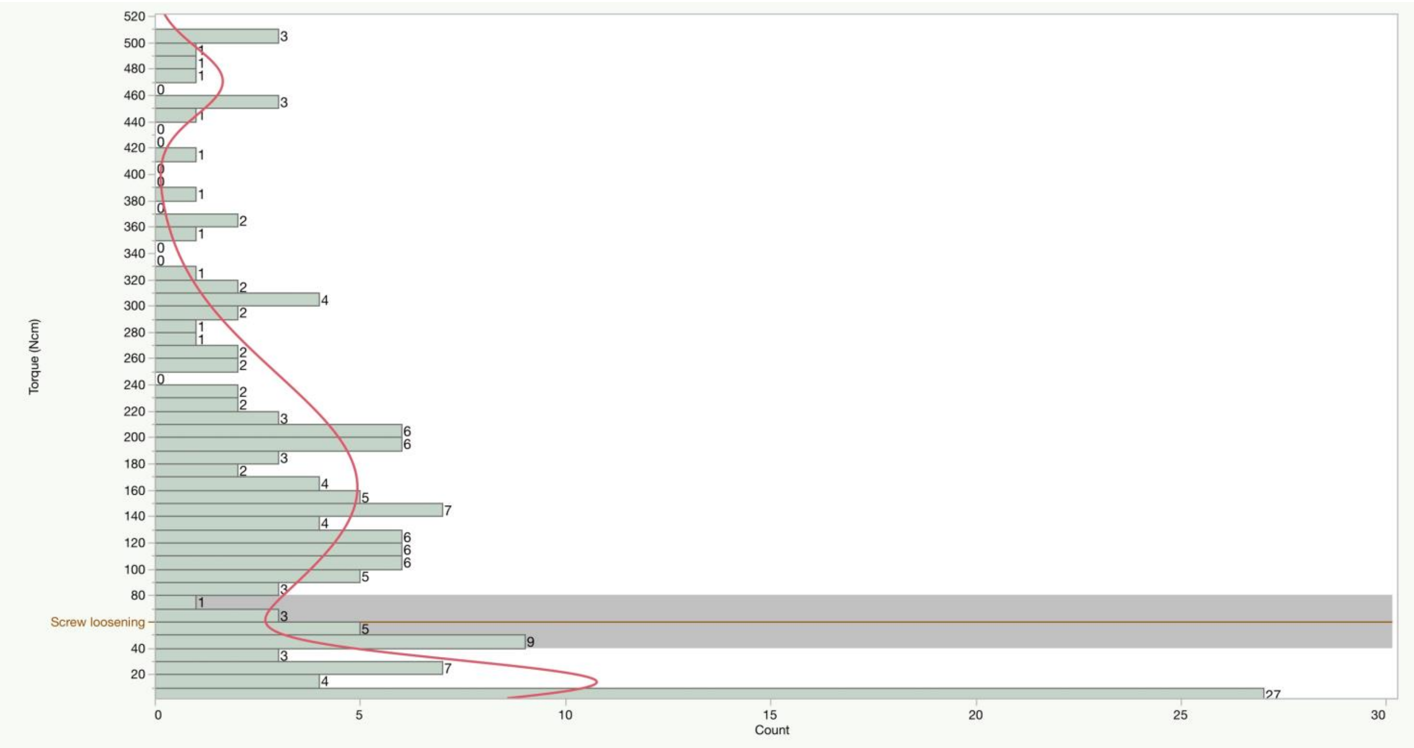

Figure 5:

Linear regression analysis of peri-screw osteolysis in radiographs with ln-transformed torque values shows a significant negative association.

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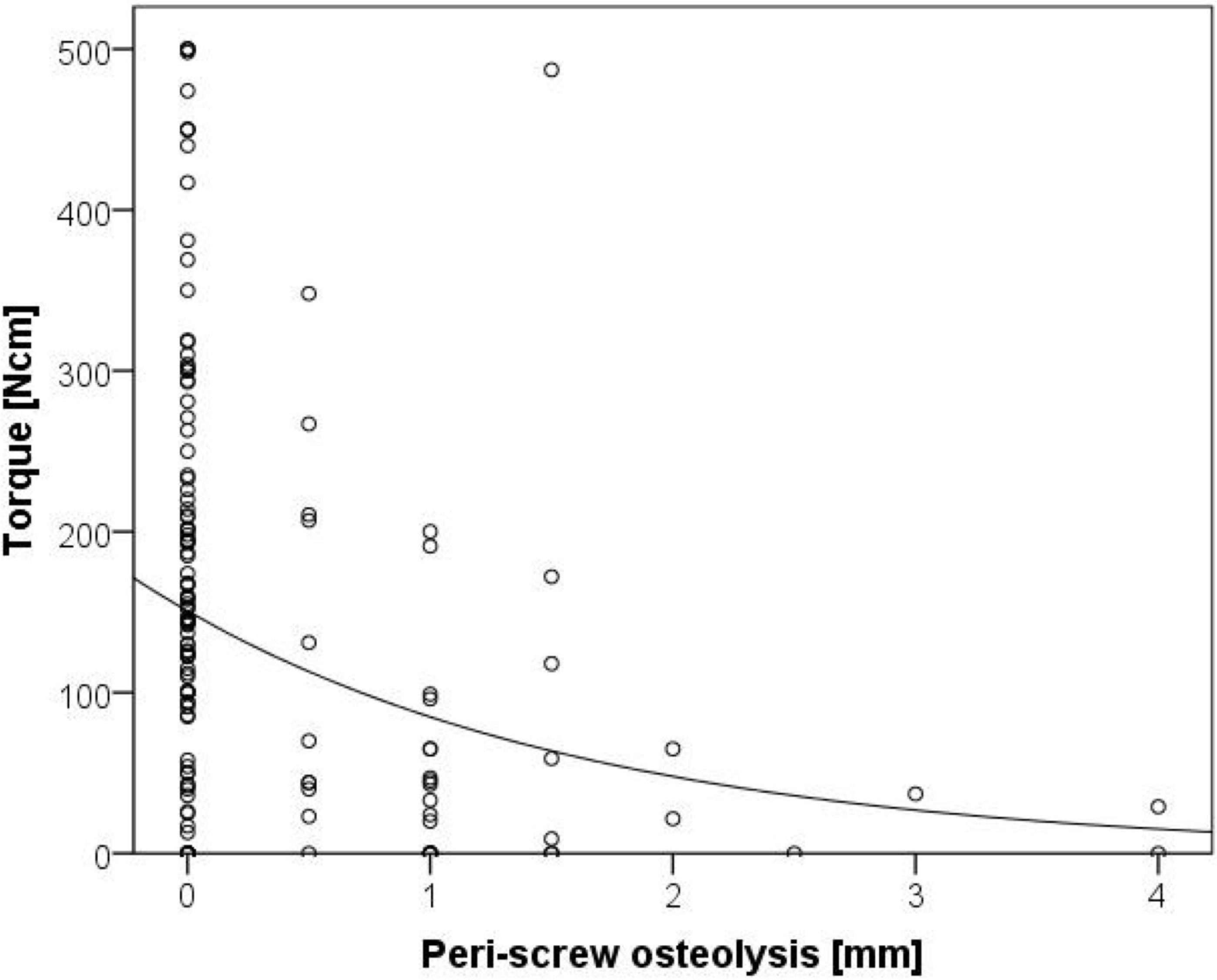

Torque [Ncm]
500
400
300
200
100
0
0
1
2
3
4
Peri-screw osteolysis [mm]

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Figure 6:

Linear regression analysis of peri-screw osteolysis in CT with ln-transformed torque values. There is a significant negative association in both readers with good interclass correlation.

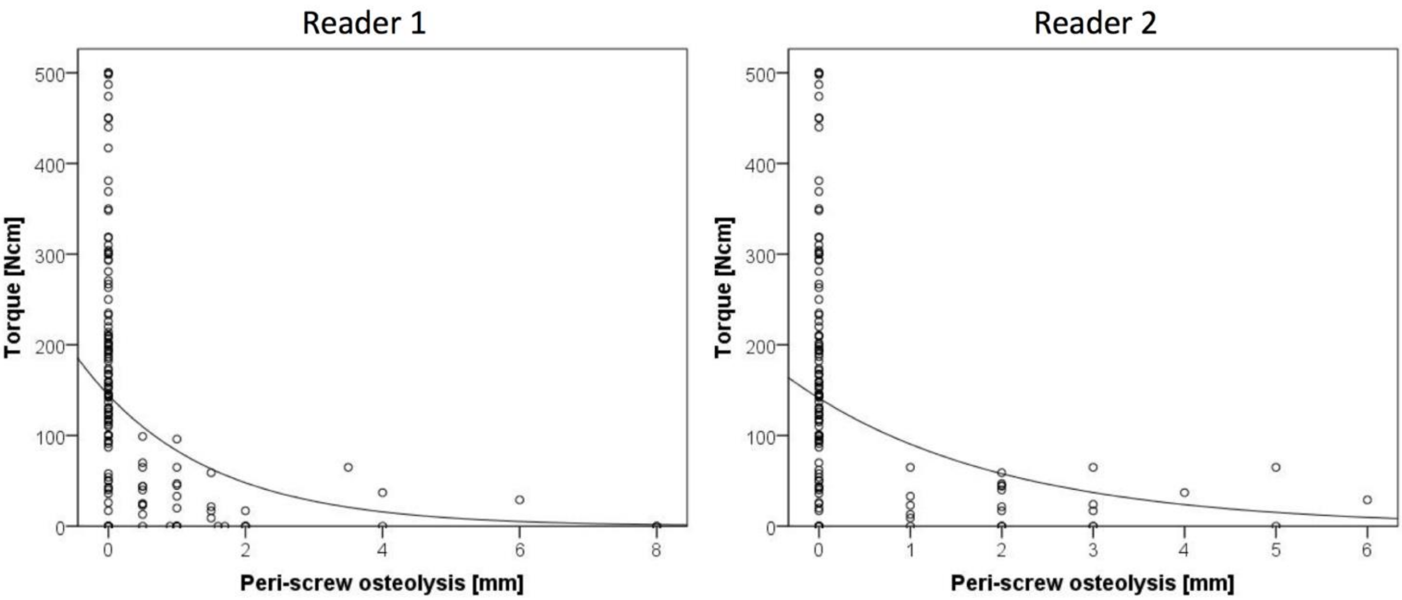

Figure 7:

Mean unscrew torques for both, screws with and without peri-screw edema in MRI. For both readers, there was a significant reduction of unscrew torque in cases with peri-screw edema.

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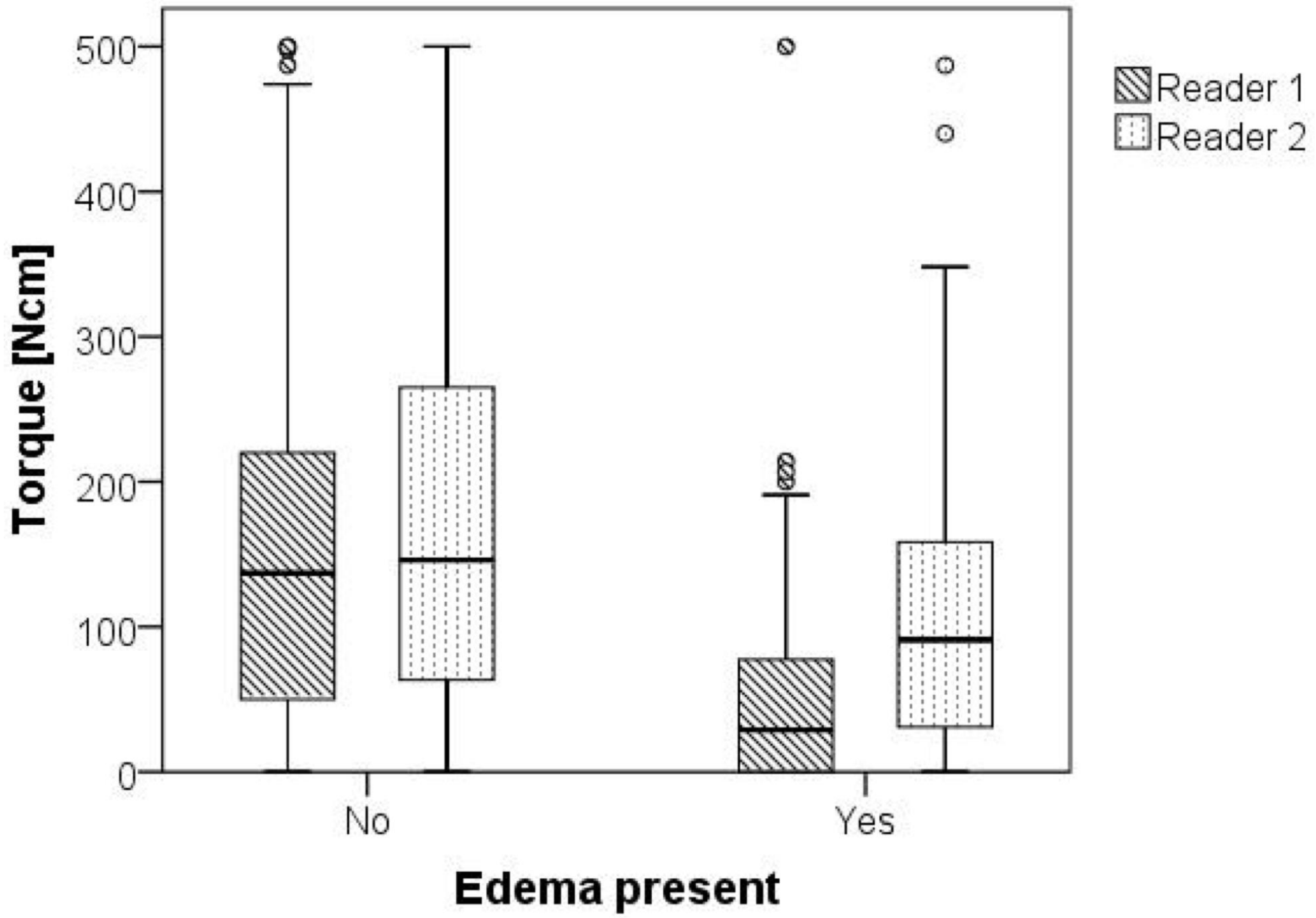

Tables

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Table 1:

Sensitivity and Specificity of different diagnostic modalities with varying definitions of a loose screw (<40 Ncm, <60 Ncm and <80 Ncm)

Predictor		Torque <80Ncm Count	Torque >80Ncm Count	Sens.	Spec.	Torque <60Ncm Count	Torque >60Ncm Count	Sens.	Spec.	Torque <40Ncm Count	Torque >40Ncm Count	Sens	Spec
Peri-screw osteolysis radiographs (Reader 1)	No instability predicted	22	81			22	81			16	87		
	Instability predicted	30	12	**57.7%**	**87.1%**	26	16	**54.2%**	**83.5%**	20	22	**55.6%**	**79.8%**
Peri-screw osteolysis CT (Reader 1)	No instability predicted	19	91			19	91			13	97		
	Instability predicted	39	2	**67.2%**	**97.8%**	35	6	**64.8%**	**93.8%**	30	11	**69.8%**	**89.8%**
Peri-screw osteolysis CT (Reader 2)	No instability predicted	22	85			20	87			13	94		
	Instability predicted	25	0	**53.2%**	**100.0%**	22	3	**52.4%**	**96.7%**	18	7	**58.1%**	**93.1%**
Peri-screw edema MRI (Reader 1)	No instability predicted	39	90			36	93			28	101		
	Instability predicted	20	7	**33.9%**	**92.8%**	19	8	**34.5%**	**92.1%**	15	12	**34.9%**	**89.4%**
Peri-screw edema MRI (Reader 2)	No instability predicted	27	68			23	72			17	78		
	Instability predicted	19	20	**41.3%**	**77.3%**	18	21	**43.9%**	**77.4%**	13	26	**43.3%**	**75.0%**

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